

## Environmental and Social Data Sheet

### Overview

Project Name:	<i>COVID-19 VACCINE RDI SPAIN</i>
Project Number:	<i>2021-0440</i>
Country:	<i>Spain</i>
Project Description:	<i>The project supports the company's investments to develop vaccines against severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2).</i>
EIA required:	no
Project included in Carbon Footprint Exercise <sup>1</sup> :	no

### Environmental and Social Assessment

#### Environmental Assessment

The project mainly concerns investments in RDI that are expected to be carried out in the Promoter's existing facilities or other research centres already authorised for the same purpose.

Investments are also expected to be made into the furnishing and validation of an existing manufacturing facility, together with associated laboratory and manufacturing equipment. The shell of the facility has already been built and the facility is to be furnished to enable vaccine production and final product formulation. The Promoter has an integrated environmental management policy and effective operating procedures in place which are in line with best industry practice.

The facility falls under the annex II of the EIA directive (2014/52/EU), referring to the manufacture of pharmaceutical products, the facility and project has been screened out. In line with the applicable national laws, the promoter has obtained all the necessary permits and authorisations from the competent authorities that are required to proceed with the construction of the new facility. The afore-mentioned permits and authorisations have been issued in compliance with Directive 2014/52/EU amending the EIA Directive 2011/92/EU.

The production process of medicinal products has limited environmental impact and the authorised products are subject to environmental risk assessments under directive 2001/83/EC as deemed necessary, in order to complete the relevant marketing authorisation application. The project is located in an area reserved for industrial use with no impact on Natura 2000 sites. The project will be carried out according to state-of-the-art technology and will take into consideration environmentally friendly, low energy-and-resource consuming technologies.

<sup>1</sup> Only projects that meet the scope of the Carbon Footprint Exercise, as defined in the EIB Carbon Footprint Methodologies, are included, provided estimated emissions exceed the methodology thresholds: 20,000 tonnes CO<sub>2</sub>e/year absolute (gross) or 20,000 tonnes CO<sub>2</sub>e/year relative (net) – both increases and savings.

Luxembourg, 30 September 2021

### **Other Environmental and Social Aspects**

The promoter is audited, certified and authorised by the relevant Spanish authorities for the manufacturing and release of human medicinal products. Furthermore, its quality control laboratory is qualified by the Competent National Authority as well as relevant international bodies. The promoter has a robust quality management system and effective operating procedures which have been duly audited by the Competent Authorities and are in-line with ICH and GMP standards. The new facility will comply with the aforementioned standards.

The project supports research into the virus SARS-CoV-2 that causes COVID 19 and it therefore contributes to the EU coordinated response to the COVID 19 crisis. Successful vaccines to combat the disease pandemic reinforce public health sectors and mitigate the socio-economic impact of the disease globally.

The Bank will require that the promoter supplies copies of all the applicable and relevant authorisation documents during the due-diligence procedure.

### **Conclusions and Recommendations**

The project will not result in any significant additional negative environmental and social impacts. It is therefore considered acceptable for the Bank financing in environmental and social terms.